

REMARKS**Introductory Comments**

The following remarks include references to settled litigations involving U.S. Patent No. 6,605,300, the grandparent patent to the instant application. The recently settled litigations are:

1. *Shire Laboratories, Inc. v. Barr Laboratories, Inc.*, in the United States District Court for the Southern District of New York, Civil Action No. 03-CV-1219-PKC; and
2. *Shire Laboratories, Inc. v. Barr Laboratories, Inc.*, in the United States District Court for the Southern District of New York, Civil Action No. 03-CV-6632-PKC.
3. *Shire Laboratories, Inc. v. Impax Laboratories, Inc.*, in the United States District Court for the District of Delaware, Civil Action No. 03-CV-01164-GMS;
4. *Shire Laboratories, Inc. v. Impax Laboratories, Inc.*, in the United States District Court for the District of Delaware, Civil Action No. 05-CV-00020-GMS;

These litigations also concern Applicant's U.S. Patent No. 6,322,819, the parent application of the '300 patent. Applications for reissue of the '300 and '819 patents (Serial Nos. 11/091,010 and 11/091,011, respectively) are co-pending.

The Supplemental Information Disclosure Statement filed concurrently herewith provides additional information regarding these litigations. Corresponding submissions have been made in the '819 and '300 reissue applications.

The claims of the '300 patent are now subject to allegations of invalidity in a recent litigation, *Shire Laboratories Inc. v. Teva Pharmaceutical Industries Ltd.*, United States District Court, Eastern District of Pennsylvania, Case No. 2:06-cv-00952-SD (a copy of the court docket

and pleadings for this case are submitted in the accompanying Supplemental Information Disclosure Statement at **SB/08 Tabs CM5-CV5**).

I. Amendments to the Specification

Amendments similar to those below to the specification were made in the '300 patent reissue application (U.S. Patent App. No. 11/091,010). The Examiner is respectfully directed to the Response to Office Action filed May 2, 2006 and the Response to Non-Final Office Action filed January 10, 2007 in the '300 reissue application (copies of which are provided at **SB/08 Tab CM3** and **SB/08 Tab CZ5**, respectively, and are listed in the accompanying Form PTO/SB/08).

A. Brief Description of the Drawings

The brief descriptions of Figures 4, 5 and 6 in the specification as filed and the '300 patent recite that these figures show exemplary plots (percent drug release versus time) of the immediate release component and the delayed release components for embodiments of the patented drug delivery system (specification as filed at page 10, line 22 through page 11, line 6; '300 patent (at **SB/08 Tab AD**) at column 6, lines 50-61). These are obvious errors. They are corrected by deleting the phrase "the immediate release component and." Each figure shows a plot for delayed release only, not for both immediate and delayed release components.

Figures 4, 5 and 6 correspond to Examples 2, 3, and 4, respectively. Each of these examples clearly relates to delayed release pellets only. Immediate release is shown in Example 1 and Figure 3. Example 2 describes pellets that were coated such that "the enteric coating delayed the drug release from the coated pellets..." (specification as filed at page 18, lines 5-6; the '300 patent at

column 11, lines 9-10). Figure 4 shows the drug release profile of the pellets exemplified in Example 2: “The drug release profile of the coated pellets of this example [Example 2] is shown in FIG. 4” (specification as filed at page 18, line 16; ‘300 patent at column 11, lines 23-24.) Figure 4, on its face, shows a delayed release, beginning at about 2 hours, as opposed to Figure 3 (Example 1), which shows an immediate release of the drug, beginning at 0 minutes. Thus, the amendment to the brief description of Fig. 4 is supported by the specification, is not new matter, and would be apparent to a person of ordinary skill in the art.

The amendments to the brief descriptions of Figures 5 and 6 are similarly supported, are not new matter, and would be apparent to the artisan.

More specifically, the corrections to the paragraphs beginning at page 10, line 22 (Figure 4); page 11, line 1 (Figure 5); and page 11, line 4 (Figure 6) of the specification as filed, corresponding to column 6, line 49; column 6, line 53; and column 6, line 58 of the ‘300 patent, are based on the disclosures in the Figures themselves, and in the specification as filed in the instant application at page 17, line 23 through page 18, line 16 (Figure 4); page 18, line 17 through page 19, line 7 (Figure 5); and page 19, lines 8-30, corresponding to the ‘300 patent at column 10, line 59 to column 11, line 11; column 11, lines 25-57; and column 11, line 58 to column 12, line 26.

B. Example 2: MASL Pellets, Fluid Bed Processor, and 20 microns

(1) MASL Pellets

The MASL enteric coated pellets disclosed in Example 2 are erroneously described as “PPA” pellets at page 18, line 4 of the specification as filed and at column 11, line 6 of the ‘300

patent. The amendment at page 18, line 4 of the specification as filed in the instant application replaces “PPA” with “MASL,” and is a correction of this plain error.

The Examiners in the ‘300 and ‘819 reissue applications stated that this inadvertent error is correctable by a Certificate of Correction (*see*, Responses to Non-Final Office Action filed January 10, 2007, at **SB/08 Tab CY5** (‘819 reissue application) and **SB/08 Tab CZ5** (‘300 reissue application). *See also Koito Mfg. Co.*, 381 F.3d at 1153; MPEP 2163.07). Thus, the PTO has determined that this correction is not new matter. *See* 35 U.S.C. §255 and MPEP 1481 (a Certificate of Correction only involves “minor” changes not involving new matter).

In all but one instance, the pellets are correctly identified in Example 2 as MASL pellets. The other examples in the specification also support the conclusion that the pellets were inadvertently described as PPA pellets. The delayed release pellets described in Example 2 were made using the MASL pellets of Example 1 (specification as filed at page 17, lines 24-25, corresponding to the ‘300 patent at column 10, lines 60-61). PPA pellets are not described anywhere in Example 1. The coated delayed release pellets described in Example 4 were made using MASL pellets from Example 2 or Example 3 (specification as filed at page 18, lines 21-24, corresponding to the ‘300 patent at column 11, lines 33-36). PPA pellets are not described anywhere in Examples 3 and 4. Thus, the only pellets actually disclosed in the examples are MASL pellets. The one inadvertent use of “PPA” is an obvious oversight, and its correction is not new matter.

(2) Fluid Bed Processor

The precision coater used with the fluid bed processor in Example 2 (specification as filed at page 17, line 27, corresponding to the ‘300 patent at column 10, line 65) was inadvertently

identified as model MP2/3 from Niro, Inc. The replacement of “(MP2/3, Niro, Inc.)” with “(see Example 3 and Example 4)” in Example 2 corrects this error, and is not new matter.

The Examiners in the ‘300 and ‘819 reissue applications have both stated that this inadvertent error is correctable by a Certificate of Correction (*see*, Responses to Non-Final Office Action filed January 10, 2007, at **SB/08 Tab CY5** (‘819 reissue application) and **SB/08 Tab CZ5** (‘300 reissue application)). Thus, the PTO has determined that no new matter is added by way of these amendments.

In fact, a Glatt GPGC-15 precision coater was used in each of Examples 2-4; the Niro MP2/3 was not used. *See* Examples 3 and 4, specification as filed at page 18, line 20 and page 19, line 11. Example 2 cites a reference number “AR98I25-4” (specification as filed at page 18, line 7, corresponding to column 11, lines 10-11 of the ‘300 patent). Applicant’s Analysis Report AR98I25 discloses that reference number AR98I25-4 corresponds to pellets having lot number 980057. The equipment used to make this lot of pellets included a Glatt Air Technology Model GPGC-15 precision coater, not the Niro MP2/3.¹

The replacement of “(MP2/3, Niro, Inc.)” with “(see Example 3 and Example 4)” in Example 2 is not new matter because: (1) as amended, one of ordinary skill in the art, considering the specification as a whole, would at least use the only other (and correct) processor disclosed in the specification as filed in the instant application (and the ‘300 patent specification (i.e., a Glatt

¹ This and other such reports are confidential documents of the Applicant. Applicant believes that it is not necessary to submit actual internal reports in order to support the correction of errors in the specification as requested herein, or to satisfy the requirements of 37 C.F.R. § 1.56. Subject to appropriate confidentiality protections, the Applicant will submit the underlying reports in another supplemental information disclosure statement, if requested to do so.

GPGC-15 processor)), and (2) the Glatt and Niro processors are both suitable for the production of pellets according to Example 2. Accordingly, this amendment is not new matter.

(3) The deletion of “(20 μ)” from Example 2

The specification has been amended to remove the parenthetical “(20 μ).” This amendment was also submitted in the ‘819 and ‘300 reissue applications. The Examiner in the ‘300 reissue application has indicated that this inadvertent error is correctable by Certificate of Correction. The ‘819 Examiner is silent regarding this error. Thus, the only position expressly taken by the Patent Office is that this error is correctable by Certificate of Correction.

Deleting “(20 μ)” is a correction that is plain, and is supported by the rest of the original disclosure. The specification elsewhere expressly discloses a coating of greater than 20 μ . See the specification as filed at page 7, lines 8-10, corresponding to the ‘300 patent at col. 4, ll. 54-57: “application of a thicker coating (greater than 20 μ)”; the specification as filed at page 6, lines 22-25 corresponding to the ‘300 patent at col. 4, ll. 35-39 (10-20 μ is “the typical amount,” i.e., not the thickness of the invention). The recitation of 20 μ *per se* in Example 2, is the only such instance in the specification. The remainder of the specification makes it clear that a coating thickness according to the invention is greater than 20 μ , not precisely 20.

Correction of an error is not new matter when the error and its correction would be clear to a person of ordinary skill in the art. See *Koito Mfg. Co. v. Turn-Key-Tech*, 381 F.3d 1142, 1153 (Fed. Cir. 2004); MPEP 2163.07; *In re Oda*, 443 F.2d 1200 (CCPA 1971); MPEP 2163.07. Thus, as the PTO previously determined, the deletion of “(20 μ)” is not new matter.

C. Table 2

Table 2 incorrectly recites the amount (%) of MASL as 40.00 instead of 70.00. The amendment to the first entry in Table 2 (specification as filed in the instant application at page 18, line 10, corresponding to the '300 patent at column 11, line 16, in Table 2) corrects this error. The error is clearly typographical, because the values do not total 100%. For example, the values in corresponding Tables 1 and 3 (in Examples 1 and 3, respectively) are headed "Amount (%)" and their values total 100.

This amendment was also made in the '819 and '300 reissue applications. The Examiner in the '819 reissue application has indicated that this inadvertent error is correctable by Certificate of Correction whereas the '300 reissue Examiner is silent on this issue (*see*, Responses to Non-Final Office Action filed January 10, 2007, at **SB/08 Tab CY5** ('819 reissue application) and **SB/08 Tab CZ5** ('300 reissue application)). Thus, the only position expressed by the PTO is that this correction is not new matter.

D. Table 3

Table 3, in conjunction with Example 3, discloses a delayed release pellet formulation. Although Table 3 correctly lists the pellet ingredients, the values listed in Table 3 are incorrect. The amendment to Table 3, deleting these values, corrects this error.

This amendment was also made in the '819 and '300 reissue applications. The Examiner in the '819 reissue application has indicated that this inadvertent error is correctable by Certificate of Correction whereas the '300 reissue Examiner is silent on this issue (*see*, Responses to Non-Final Office Action filed January 10, 2007, at **SB/08 Tab CY5** ('819 reissue application) and **SB/08 Tab**

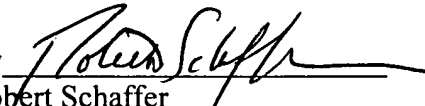
CZ5 ('300 reissue application)). Thus, the only position expressed by the PTO is that this amendment is not new matter.

CONCLUSION

No new subject matter has been added as a result of the amendments. Entry of the amendments prior to consideration of the application on the merits is respectfully requested.

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Respectfully submitted,

By 
Robert Schaffer
Registration No.: 31,194
DARBY & DARBY P.C.
P.O. Box 5257
New York, New York 10150-5257
(212) 527-7700
(212) 527-7701 (Fax)
Attorneys For Applicant